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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,950	12/26/2001	Bhami Shenoy	VPI/00-08	9344

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EXAMINER	
FETTEROLF, BRANDON J	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/034,950	SHENOY ET AL.	
	Examiner	Art Unit	
	Brandon J Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04/02/2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-78* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-4, 6, 8-10, 17-18, 24-30, as specifically drawn to an antibody, wherein said antibody's β-sheet structural content is determined by correlation spectra and FTIR, classified in class 530, subclass 387.3.

2. Claims 1-3, 5-11, 17-18, 24-30, as specifically drawn to an antibody, wherein said antibody may be a therapeutic or a carrier-free pharmaceutical controlled release antibody, classified in class 530, subclass 387.3, 388.15.

3. Claims 1-3, 12, 17-18, 24-30, as specifically drawn to an antibody, wherein said antibody is anti-idiotypic, classified in class 530, subclass 387.3, 388.15.

4. Claims 1-3, 13, 17-18, 24-30, as specifically drawn to an antibody, wherein said antibody is mono-specific and can bind to different epitopes, classified in class 530, subclass 388.9.
(Upon election of Group 4, applicant must further choose ONE antibody from those listed in Claim 13, as each antibody is a distinct invention, NOT a species)

5. Claims 1-3, 14, 17-18, 24-30, as specifically drawn to an antibody, wherein said antibody is mono-specific and can bind to different epitopes, classified in class 530, subclass 388.1.
(Upon election of Group 5, applicant must further choose ONE antibody from those listed in Claim 14, as each antibody is a distinct invention, NOT a species)

6. Claims 1-3, 15, 17-18, 24-30, as specifically drawn to an antibody, wherein said antibody is generic and can bind to a plethora of different epitopes, classified in class 530, subclass 388.3.
(Upon election of Group 6, applicant must further choose ONE antibody from those listed in Claim 15, as each antibody is a distinct invention, NOT a species)

7. Claims 1-3, 16, 17-18, 24-30, as specifically drawn to an antibody, wherein said antibody is an antibody for treating a disease, classified in class 530, subclass 387.1.
(Upon election of Group 7, applicant must further choose ONE antibody for treating a disease from those listed in Claim 16, as each antibody is a distinct invention, NOT a species)

8. Claims 19-20, 24-30, as specifically drawn to a dried antibody crystal, classified in class 530, subclass 388.1.

9. Claims 21, 24-37, 76, as specifically drawn to a composition for the release of an antibody, wherein said composition comprises an antibody and a polymeric carrier, classified in class 424,subclass 178.1; class 436, subclass 528.

10. Claims 22, 24-31, 38-39, 76, as specifically drawn to a formulation, wherein said formulation comprises an antibody and albumin or one ingredient, classified in class 530, subclass 362; class 436, subclass 528.

11. Claims 23-39, 76, as specifically drawn to a composition, wherein said composition comprises a formulation, albumin or one ingredient and a polymeric carrier, classified in class 424, subclass 178.1; class 436, subclass 528.

12. Claim 40, as specifically drawn to a method of treating a mammal by administering an antibody crystal, classified in class 424, subclass 130.1

13. Claims 41-42, 77-78, as specifically drawn to a method of administering a composition or formulation for treating a mammal, classified in class 424, subclass 178.1.
(Upon election of Group 13, the applicant must further choose ONE composition or formulation from those listed in Groups 9, 10, 11, as each composition or formulation is a distinct invention and NOT a species)

14. Claims 43-68, as specifically drawn to a method of crystallizing a dried antibody by large-batch crystallization, classified in class 424, subclass 130.1; class 530, subclass 421.
(Upon election of Group 14, the applicant must further choose ONE mode of drying from those listed in Claim 44, as each mode of drying is a distinct invention, NOT a species)

15. Claim 69, as specifically drawn to a method of purifying a protein by affinity matrix purification, classified in class 424, subclass 130.1; class 530, subclass 413.

16. Claims 70-73, as specifically drawn to a diagnostic kit for the *in vitro* detection of an antigen, classified in class 530, subclass 388.1, 389.1.

17. Claim 74, as specifically drawn to a method of crystallizing an antibody via large-batch crystallization, classified in class 424, subclass 130.1; class 530, subclass 421.

18. Claim 75, as specifically drawn to method of producing a solution of antibody using transgenic milk, classified in class 800, subclass 7.

The inventions are distinct, each from the other because of the following reasons:

different modes of operation, different functions and different effects. For example, Group 1 and Group 8 are both drawn to an antibody crystal, wherein the antibody of Group 8 is a dried antibody requiring an extra step in the crystallization process. Furthermore, Group 1 and Group 11 both contain an antibody as a product, wherein the product of Group 11 comprises an antibody along with the one ingredient and a polymeric carrier.

The inventions of Groups 12-15 and 17-18 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosage and/or schedules used, response variables, and criteria for success. For example, Group 12 and Group 13 are both drawn to a method of treating a mammal with an agent, wherein said agent is an antibody crystal for Group 12 and a composition for Group 13.

The inventions of Groups 9-11 and the method of Group 13 are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process as claimed can be practiced with materially different products such as with the antibodies of Group 9 or 10 or 11.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for the other, restriction for examination purposes as indicated is proper.

Species Election

Groups 1-2 (Claim 8) are generic to a plurality of disclosed patentably distinct species comprising distinct antibodies such as:

Chimeric antibodies, humanized antibodies, non-glycosylated antibodies, ect..

Groups 1-2 (Claim 9) are generic to a plurality of disclosed patentably distinct species comprising distinct immunoglobulins such as:

IgG, IgM, IgA , IgD, etc..

Groups 1-2 (Claim 10) are generic to a plurality of disclosed patentably distinct species comprising distinct immunoglobulins such as:

IgG1, IgG2, IgG3, IgG4, ect..

Groups 1-7 (Claim 18) are generic to a plurality of disclosed patentably distinct species comprising a distinct labeled crystal such as:

1) Radiolabels
2) Enzyme labels
3) Toxins
4) Magnetic agents
5) Drug conjugates

Groups 1-11 (Claims 24-30) are generic to a plurality of disclosed patentably distinct species comprising distinct concentrations such as:

1 mg/ml, 10.1 mg/ml, 20 mg/mL, ect

Groups 9, 11 (Claims 34-37) are generic to a plurality of disclosed patentably distinct species comprising distinct polymeric carrier such as:

Biodegradable, biocompatible, poly (cyanoacrylates), poly (depsipeptide), ect..

Groups 10, 11 (Claim 39) are generic to a plurality of disclosed patentably distinct species comprising distinct stabilizers such as:

Sucrose, trehalos, lactitol, gelatin, ect..

Group 14 (Claims 45-47) is generic to a plurality of disclosed patentably distinct species comprising distinct temperature ranges such as:

1) 4 °C to 37 °C

2) –22 °C to 61 °C

3) 22 °C to 61 °C

Group 14 (Claims 48-51) is generic to a plurality of disclosed patentably distinct species comprising distinct buffer pH's ranges such as:

1) 1.9 to 11.1

2) 1.9 to 4.0

3) 3 to 10

4) 9.0 to 11.1

Group 14 (Claims 52-55) is generic to a plurality of disclosed patentably distinct species comprising distinct concentration ranges of polyethylene glycol such as:

1) 5% to 40%

2) 1.9% to 80%

3) 1.9% to 5%

4) 20% to 81%

Group 14 (Claims 56-59) is generic to a plurality of disclosed patentably distinct species comprising distinct size ranges of polyethylene glycol such as:

1) 200 to 20000

2) 200 to 80,000

3) 200 to 400

4) 400 to 80,000

Group 14 (Claims 60-64) is generic to a plurality of disclosed patentably distinct species comprising distinct concentration ranges of the antibody such as:

1) 0.01 mg/ml to 4 mg/ml
2) 10 mg/ml to 25mg/ml
3) 3 mg/ml to 200 mg/ml
4) 25 mg/ml to 500 mg/ml

Group 14 (Claims 65-68) is generic to a plurality of disclosed patentably distinct species comprising distinct concentration ranges of the buffer such as:

1) 10 mM to 400 mM
2) 0 mM to 4 M
3) 0 mM to 2 M
4) 1 M to 4 M

The products of the above species represent separate and distinct molecules with different structures and functions such that one species could not be interchanged with the other. As such, each species would require different searches and consideration of different patentability issues.

Additionally, the steps and reagents of the above species are completely distinct and impart different biological functions and use such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Applicant is required under 35 U.S.C 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of

an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant transverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior are, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571)-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

GARY NICKOL
PRIMARY EXAMINER